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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,935 06/01/99 TAKEBE

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EXAMINER

AFREMOVA, V

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

10/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/284,935

Applicant(s)
Takebe et al.

Examiner
Vera Afremova

Group Art Unit
1651



☒ Responsive to communication(s) filed on Aug 3, 2000

- ☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-8 as amended (Paper No. 10 filed 8/03/2000) are pending and under examination.

Claim Rejections - 35 U.S.C. § 112

Indefinite

Claims 1-8 as amended remain rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 5 as amended are rendered indefinite by the phrase “*adding* at most 50% *by weight of water* to said resultant”. First, it is unclear as amended what exactly is added. Is it water? Or is something else added in amounts comparative to weight of water or to moisture contents? When this phrase/step is interpreted as being directed to addition of water, it remains indefinite with regard to a compound which weight is compared to weight of added water. Is it a resultant from a prior step? Is it a koji mold? Is it a grain material? Would koji mold, grains or resultant be a dry composition? Is water content adjusted to 50% moisture content in the whole composition during this step?

Claims 3 and 6 are rendered indefinite by the phrase “said resultant” since there at least two “said” resultants in the independent claims as amended. And it is unclear which resultant is intended to contain “beneficial microorganisms” and/or to what “resultant” these “beneficial microorganisms” are intended to be added. Further, with respect to claims 3, 4, 6, 7 and 8 it

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remains unclear where a "beneficial microorganism contained in said resultant" is coming from. Was it in the grains? Was it in the water added?

Claim 2 remains indefinite because it is unclear what is "resistant" starch or what makes starch to be "resistant". How to select a "resistant" starch? Would be any difference between the claimed resistant starch and starch as inert absorbent?

New matter

Claims 1-8 are rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation directed to a range of concentration such as "**at most 50%** by weight" has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of water or moisture content which would be **at most or no more than 50%**. There is only one particular disclosure about addition of water to a product in amount 50 % by weight (see specification page 12, line 24) wherein these amounts are not limited to a condition of being "at most" or no more than 50%. On the contrary, the meaning of the disclosed example is directed to the idea that these amounts are not critical and might be, "for instance, 50% by weight". This is not sufficient support for the new limitation directed to

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addition of water in amounts such as "at most 50%" or no more than 50%. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of a range of concentration such as "at most 50%" is considered to be the insertion of new matter for the above reasons.

Response to Arguments

Applicant's arguments filed 8/03/2000 have been fully considered however not all applicants' arguments were found persuasive for the reasons below.

Claim Rejections - 35 U.S.C. § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3 remain rejected under 35 U.S.C. 102(b) as being anticipated by JP 7-23725 [N] as explained in the prior office action and for the reasons below.

Claims are directed to a product for promoting growth of beneficial microorganisms wherein the product is obtained by a process encompassing steps of inoculating grains with koji mold to create a resultant, adding water to the resultant and removing phytic acid from the whole preparation. Some beneficial microorganisms are present within the resultant/whole preparation.

JP 7-23725 [N] teaches a product obtained by the process comprising steps of inoculating grains with koji mold, adding water to bring the moisture content to levels as to enable

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proliferation of koji mild and fermentation of grains until phytic acid is sufficiently reduced or removed (abstract). The cited method encompasses the same active steps as claimed and, thus it inherently results in the possession of identical product as claimed. Some beneficial microorganisms are reasonably expected to be present within the whole preparation since the initial soybean refuse was not sterilized but only steamed and it was further fermented to promote proliferation of microorganisms as disclosed by the cited patent.

With regard to JP 7-23725 applicants argue that the cited reference does not teach “beneficial microorganism” in the product. This is not found persuasive. The applicants’ definitions are not particularly clear that “beneficial microorganism” and “koji mold” are distinct microorganisms or that the “koji mold(s)” are excluded from the group of “beneficial microorganisms”. Koji molds are used in preparation of food and, therefore, they are reasonably expected to help to “sustain health of living being” as claimed and as disclosed. In addition, the components which are used in the process of making the claimed product are not sterile as claimed and, thus, at least some amounts of generic “beneficial microorganisms” are expected to contaminate or to be “contained” in the grains or in the “resultant”, for example. Another applicants’ argument is directed to the idea that the cited patent is silent with regard to a particular amount of water to be added to a mixture of grains and molds. This might be convincing as related to a method of making a product. However, it is unclear as claimed and as disclosed what are water contents of the final product and, thus, this limitation is not a critical element for a product made by a process, particularly in view that product is a generic microbial

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growth-promoting composition and the cited product was made by addition of water in amounts sufficient to enable proliferation of microorganisms as particularly taught by the cited reference (abstract). Moreover, the applicants' final product appears to be dry as disclosed (see Fig. 2)

The rejection of claims 5 and 6 under 35 U.S.C. 102(b) as being anticipated by JP 7-23725 [N] has been withdrawn because the method claims as amended require a step of adding water in particular amounts of 50%. Applicants are hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection of claims 5 and 6 under 35 U.S.C. 102(b) as being anticipated by JP 7-23725 [N]. However, removal of new matter might result in the reinstatement of the art rejection(s).

Claims 1 and 3-8 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 4,308,284 [A] in view of JP 7-23725 [N] as explained in the prior office action and for the reasons below.

Claims are directed to a process and to a product obtained by the process comprising steps inoculating grains with koji mold and adding no more than 50% of water to the mixture of grains and molds thereby hydrolyzing proteins and removing phytic acid. Some claims are further drawn to addition of beneficial microorganisms. Some claims are further drawn to beneficial microorganisms being yeasts of lactobacilli.

The cited references are relied upon as explained in the prior office action. US 4,308,284 [A] clearly teaches a process and a product obtained by the process comprising steps of

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inoculating grains with koji mold, adding water and adding beneficial microorganisms such as yeasts of lactobacilli (abstract; col.7, lines 5-30; col.3, lines 61-64; col.4, lines 44-46; col.5, line 21). The step of removing a phytic acid contained in the grains is inherently present in the method of '284 in view of the teaching by JP 7-23725 [N] since both patents disclose fermentation of the same grains (soybeans) with the same koji molds as claimed. Therefore, the cited method as disclosed by '284 comprises identical steps as the presently claimed method and, thus it results in the possession of identical product as claimed particularly in view that the cited patent teaches a promotion of growth of beneficial yeasts and lactobacilli (col.5, line 26).

Applicants argument that it is improper to use a teaching of additional reference to demonstrate an inherent element is not convincing since the applicants' method as claimed and as disclosed encompasses steps of hydrolyzing proteins and removing phytic acid as the result of growing microorganism on grains in the presence of water rather than a step of physical or chemical removal/separation. The amounts of phytic acid are reduced or removed by fermenting koji mold as taught by JP '725 and as presently claimed. Thus, a step of removing phytic acids is inherently present in the cited method of US'284 since the same components are combined in the same amounts during fermentation. For example: amounts of water added seem to be no more than 50 % when only 3 ml of bacterial suspension is added to a mixture of 10 kg of wheat and 100 g of koji mold as disclosed at col. 7, lines 10-15 in US '284. Some applicants' arguments appear to be directed to problems associated with production of soy sauce, miso or sake (see response page 3, last paragraph). However, these products are known to contain beneficial

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microorganisms including lactic bacteria as disclosed by applicants and as disclosed by the cited US'284. Thus, it is not clear as argued what would be a distinguishable critical structural element in the products and the methods of making beneficial microorganism growth promoting compositions/products which is claimed and which is taught by US'284.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,308,284 [A] taken with JP 7-23725 [N], JP 3-19686 [O], Remington [U] and Merck [V] as explained in the prior office action and for the reasons below.

Claims 1 and 3-8 as explained above. Some claims are further drawn to incorporation of starch into the material.

The primary references are relied upon as explained above. They are lacking a particular disclosure of incorporation of starch into a final material fermentation product. The secondary references Remington [U] or Merck [V] teach starch as inert absorbent for any pharmaceutical preparations or suitable for food industry.

Additional secondary reference JP- 3-19686 [O] is relied upon to demonstrate that a material obtained from grains fermented with koji molds is useful for promoting grow of lactic bacteria during milk fermentation.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a product obtained after grain fermentation with koji molds for proliferation of lactic bacteria with a reasonable expectation of success in promoting growth of lactic bacteria since the similar use have been taught or suggested in the prior art for lactic bacteria in milk fermentation [O]. Further, the addition of starch to a final active material or to a fermented material intended for food or pharmaceutical products is known in the art [U, V]. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

With regard to the cited references Remington [U] and Merck [V] applicants argue that the starch is added in order to hydrolyze composition in the claimed method unlike the teaching of secondary references wherein starch is an inert material. Yet, it is not clear that a “resistant” starch as claimed is an additional nutrient for beneficial microorganisms but not a delivery material intended for future use of probiotics or beneficial microorganisms.

Applicants further argue that the cited JP’686 suggests larger quantity of water to be added than the presently claimed amounts. However, the cited patent is relied to demonstrate the use of a final koji mold fermented product for promoting growth of beneficial lactic bacteria during further fermentation of milk. The similar use is disclosed by applicants, for example: at page 17, wherein no water seems to be added.

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No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

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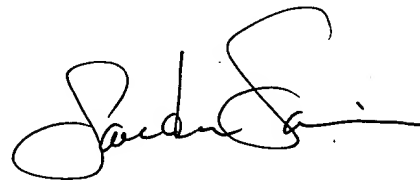
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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October 17, 2000.

V. A .

A handwritten signature in black ink, appearing to read 'Sandra E. Saucier', with a large, stylized initial 'S'.

SANDRA E. SAUCIER
PRIMARY EXAMINER